HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1397 Drug Distribution
SPONSOR(S): Homan
TIED BILLS: **IDEN./SIM. BILLS:** HB 685 CS, CS/SB 1540

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 1397 addresses pedigree paper requirements that were implemented as part of the 2003, SB 2312 reform of the Florida Drug and Cosmetic Act. The reform was in response to the Seventeenth Statewide Grand Jury[1] and the 2003 OPPAGA report[2] on drug fraud and diversion.

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug. According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900[3] out-of-state wholesalers.

The 2003 reforms in SB 2312 currently provide for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II is set to be implemented July 1, 2006. The purpose of the bill is to provide an alternative to the full pedigree paper requirements set to be implemented in phase II.

The alternative to the pedigree paper requirements in the bill provide that, until December 31, 2008, each person involved in the wholesale distribution of prescription drugs may provide a statement, in electronic form, stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer and is an “authorized distributor of record” in lieu of a pedigree paper as defined in s. 499.003(31), F.S.

HB 1397 also establishes a new type of prescription drug wholesaler permit, the “limited prescription drug veterinary wholesaler permit.” The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state to veterinarians, of veterinarian prescription drugs and prescription drugs regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.[4] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The Department of Health estimates that, with the creation of the limited veterinary wholesaler permit, there will be a yearly loss of $3,000 that will have no effect on current operations.

The effective date of the bill is July 1, 2006.

[1] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[2] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.
[3] According to the Department of Health 2003 records.
[4] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government - HB 1397 creates a new prescription drug wholesaler permit, the limited prescription drug veterinary wholesaler permit. The new permit would allow veterinary wholesalers to provide legend drugs intended for human use but limits the sales to no more than 30 percent. The bill decreases requirements for veterinary wholesalers that wish to provide legend drugs intended for human use. The Department of Health estimates a yearly loss of $3,000 of regulatory fees with the creation of the limited veterinary wholesaler permit.

B. EFFECT OF PROPOSED CHANGES:

CURRENT SITUATION – PEDIGREE PAPERS

The 2003 Legislature passed comprehensive reforms to the Florida Drug and Cosmetic Act to address drug fraud and diversion. The law currently provides for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II, full pedigree paper requirements, is set to be implemented July 1, 2006.

Currently there are two different record keeping requirements for prescription drugs in Florida. If a prescription drug is on the specified drug list wholesalers must follow one set of requirements, and if a prescription drug not listed on the "specified drug list" another set of requirements must be followed.

According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900[5] out-of-state wholesalers, of which less than ten percent are one of the three large full-line wholesalers or their distribution centers, or major full-line regional wholesalers. The remainders are secondary wholesalers that primarily buy and sell among other prescription drug wholesalers rather than to end-users such as hospitals or other health care entities, including physicians or pharmacies.

Pedigree Requirements for "Specified Drugs"

The Department of Health (DOH) determines "specified drugs" by rule. DOH publishes a "specified drug list" on their website. Specified drugs are the drugs most likely to be adulterated. There are currently 34 drugs on the "specified drug list."

There are three different regulatory options when engaged in the wholesale distribution of a specified drug. Each person who is engaged in the wholesale distribution of a specified drug must provide each wholesale distributor, upon any sale, a written statement that :

1. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or
2. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or
3. Before the wholesale distribution (sale of the prescription drug), a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and a sales invoice number of the invoice evidencing each specific unit of the specified drug.

[5] According to the Department of Health 2003 records.

Pedigree Requirements for drugs not list on the "Specified Drug List"

Wholesalers, who do not qualify as an "authorized distributor of record (see below)" purchasing prescription drugs not listed on the "specified drug list," must provide a pedigree paper, under oath, that traces the prescription drug back to the last authorized distributor of record (rather than back to the manufacturer of the drug).

"Authorized Distributor of Record"

Authorized Distributor of Record (ADR) is defined by s. 499.0121, F.S., as a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship exists when a wholesale distributor (including an affiliated group) meets the following requirements:

- Is listed on the manufacturer's current list of authorized distributors of record;
- Annually purchases at least 90 percent of all its prescription drugs directly from one manufacturer and has at least $100 million in total annual prescription drug sales;
- Makes at least 12 yearly purchases from the wholesale distributor; and
- Meets Department of Health (DOH) reporting requirements.

Pursuant to s. 499.0121, F.S., DOH publishes a list of wholesale distributors that qualify as an authorized distributor of record. Currently, there are 525 wholesalers listed.[6] Currently, each person engaged in wholesale distribution who does not meet ADR specification must prepare and provide a pedigree paper for the distribution of a prescription drug (not listed on the "specified drug list"[7]) back to the last ADR (rather than back to the manufacturer of the drug). ADR wholesalers do not have to meet this provision.

"***Affiliated Group" Designation***

Affiliated groups are defined by s. 1504 of the Internal Revenue Code of 1986. According to s. 499.0121, F.S., "affiliated groups" are composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers. Affiliated groups must:

- Disclose to the Department of Health (DOH) the names of all the members; and
- Agree in writing to provide records on prescription drug purchases by members of the same affiliated group not later than 48 hours after DOH requests such records, regardless of where the records are stored.

Warehouses within the affiliated group must comply with all federal and state wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs to only a retail pharmacy or warehouse within the affiliated group. Prescription drug wholesalers within an affiliated group are exempt from pedigree paper requirements as long as the drugs do not leave the affiliated group. The Department of Health may request all records related to purchase or acquisition of prescription drugs, and the affiliated group must make them available.

The affiliated group designation was scheduled to sunset July 1, 2006. However, the 2005 Legislature removed the sunset provision, thus during phase II of the pedigree paper reforms the affiliated group exemption will continue indefinitely.

Pedigree Papers Requirements

Currently, on July 1, 2006 the special provisions for "authorized distributor of record" will phase out and all players will be required to meet the same pedigree paper requirements.

On July 1, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug, must provide a pedigree paper defined in s. 499.003(31), F.S., to the person who receives the drug.

[6] See Department of Health Website, http://www.doh.state.fl.us/pharmacy/drugs/index.html

[7] The specified drug list is a list of prescription drugs that are most likely to be diverted. The Department of Health places drugs that meet certain requirements on the list. There are currently 34 drugs on the specified drug list.

The Department of Health (DOH) is currently in final stages of the rule-development process regarding pedigree papers, including provisions for digital pedigree papers. The next rule hearing is scheduled for April 3, 2006. Recently, DOH sent out a letter to all companies that currently have an active permit to distribute wholesale prescription drugs in Florida to remind them of the full implementation of pedigree papers July 1, 2006.

During the 2005 Legislative Session, the definition of pedigree paper was amended to clarify that a pedigree paper may be in either paper or electronic form.[8] A pedigree paper must include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.

Pedigree Papers Implementation Process

Phase I	Phase II	Proposed Legislation
Specified Drug List Pedigree *Three Options:* 1. May buy drug directly from manufacturer (no pedigree); 2. May buy drug in a closed affiliated group system; or 3. Provide a pedigree that tracks drug back to the manufacture of the drug (including lot number, invoice number, etc.). **Drugs not listed on the Specified Drug List Pedigree** Requires a pedigree that traces the prescription drug back to the last "authorized distributor of record." **Authorized Distributor of Record** Defined in statute[9] as a wholesale distributor with whom a manufacturer has established an ongoing relationship. Must meet certain criteria. **Affiliated Group Designation** Defined in statute[10] as chain drug entities that include at least 50 retail pharmacies, warehouses, and repackagers. Must meet certain criteria. May sell prescription drugs within their affiliated group without passing a pedigree paper (must provide one to the Department of Health if requested). Must pass a pedigree if selling drugs to individuals not in their affiliated group.	**All Prescription Drugs** All persons engaged in the wholesale distribution of a prescription drug must pass a pedigree paper (lot number, invoice, etc.) for all drugs. **Special provisions for "affiliated groups" still apply (see phase I).**	**All Prescription Drugs** All persons engaged in the wholesale distribution of a prescription drug must pass a pedigree paper (lot number, invoice, etc.) for all drugs. **OR** **All Prescription Drugs** Until December 31, 2008, may purchase drugs without passing a pedigree if the drug was purchased directly from the manufacturer and is an "authorized distributor of record (see phase I)." **Special provisions for "affiliated groups" still apply (see phase I).**

[8] Section 499.003(31, Florida Statutes.
[9] Section 499.0121, Florida Statutes.
[10] Section 499.0121, Florida Statutes.

EFFECT OF THE PROPOSED CHANGES – PEDIGREE PAPERS

HB 1397 creates an alternative to implementation of full pedigree paper requirements July 1, 2006.

The bill provides that, until December 31, 2008, each person involved in the wholesale distribution of prescription drugs may provide a statement, in electronic form, stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer and is an "authorized distributor of record" in lieu of a pedigree paper as defined in s. 499.003(31), F.S. The bill continues the Department of Health's publication of "authorized distributors of record" on its website.

The effective date of the bill is July 1, 2006.

CURRENT SITUATION - VETERINARIAN WHOLESALER PERMIT

Veterinary Prescription Drug Wholesaler Permits

Section 499.01, F.S., requires a permit for any person or establishment that wishes to operate as a veterinary prescription drug wholesaler. Veterinary prescription drug wholesaler is defined as any person engaged in the wholesale distribution of veterinary prescription drugs in or into Florida.[11] Veterinarian wholesalers may *only* sell drugs manufactured for animal use. If a veterinarian wholesaler wishes to sell *any* drugs manufactured for human use, a prescription drug wholesaler permit is required in lieu of a veterinarian prescription drug wholesaler permit.

EFFECT OF THE PROPOSED CHANGED – VETERINARIAN WHOLESALER PERMIT

Limited Prescription Drug Wholesaler Permit

HB 1397 establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit." The limited prescription drug wholesaler permit is created for any person who engages in the distribution, in or into the state to veterinarians, of veterinarian prescription drugs and prescription drugs regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.[12] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The bill defines any human prescription drug, regulated under s. 503(b), as an adulterated drug if it has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

The bill provides that no more than 30 percent of drug sales by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements under s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., when a prescription drug is distributed wholesale to a veterinarian.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or no more than $500 annually.

The bill requires the Department of Health (DOH) to inspect each limited prescription drug wholesaler. It authorizes DOH to order immediate closures of a limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health safety and welfare.

[11] Section 499.003(40), Florida Statutes.
[12] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drug intended for human consumption.

The Department of Health estimates that, with the creation of the limited veterinary wholesaler permit, there will be a yearly loss of $3,000 that will have no effect on current operations.

Prescription Drug Wholesalers

All prescription drug wholesalers are required to post a $100,000 bond and to file an extensive permit application that includes the submission of fingerprint cards for all key individuals associated with the wholesaler's operations in order for a criminal history check to be performed. In addition, each prescription drug wholesaler must have a designated representative who has successfully passed an examination on federal and state laws, and department rules, relating to the wholesale distribution of prescription drugs.

	Prescription Drug Wholesaler	**Limited Veterinarian Prescription Drug Wholesaler (proposed permit)**	**Veterinarian Prescription Drug Wholesaler**
Type of Prescription Drugs Dispensed	Legend drugs defined or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.	May dispense up to 30% of sales from legend drugs.	Veterinarian legend drugs only.
Required Deposit	$100,000 bond, certificate of deposit, or letter of credit	$20,000 bond, certificate of deposit, or letter of credit	None required.
Authorized yearly fees	$800 Annually s. 499.041(2)(a), F.S.	$300-$500 Annually (proposed legislation)	$500 s. 499.041(g), F.S.

BACKGROUND

Pedigree Papers

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and should contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug.

Seventeenth Statewide Grand Jury Report[13]

The Seventeenth Statewide Grand Jury report[14] released by the Office of the Attorney General, February 28, 2003, found "an alarming percentage of drugs flowing through the wholesale market have been illegally acquired" via theft from pharmacies and hospitals; purchases on the black market by individuals defrauding insurance companies and Medicaid; or illegal importation. Despite a 1993 state law that requires drugs to have documentation showing all the hands they passed through on the way to the patient, the investigative panel found that neither this law nor an updated version in 1996 has ever been fully enforced, in part due to industry objections.

Office of Program Policy Analysis and Government Accountability (OPPAGA) Report[15]

In February, 2003, the OPPAGA issued report No. 03-18 highlighting problems with counterfeit and diverted drugs in Florida. The findings of the report indicated that millions of dollars are lost due to counterfeit and diverted drugs in Florida's prescription drug wholesale industry. The report found a rise in drug cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concluded that current Florida law did not provide adequate controls over wholesale drug market practices, and current administrative and criminal penalties failed to provide an adequate deterrent.

[13] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[14] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[15] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

Florida Drug & Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, pt. 1, ch. 499, F.S., the Department of Health is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics. Wholesalers, manufacturers, and distributors of drugs or devices must be permitted by the department or otherwise exempt.[16]

Under the Florida Drug and Cosmetic Act (or the Act), any person who is at least 18 years of age or older and who can pay the permit fee, and after submission of specified information that all permit applicants must provide, with certain exceptions, may obtain a permit as a prescription drug wholesaler.[17] The applicant must not have been found guilty, regardless of adjudication, of a violation of a law that directly relates to a drug, device, or cosmetic. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler distributor located outside of Florida must be permitted by the Department of Health. The department is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state that has requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its laws to a Florida-permitted drug wholesaler.

The Florida Drug and Cosmetic Act specifies criminal penalties for violations relating to activities regulated by the department under the Act. Such criminal offenses are, with few exceptions, punishable as a second-degree misdemeanor (a maximum fine of $1,000 or 1 year imprisonment) if it is a second conviction for the violation of the Act.

The Act requires prescription drug wholesalers to maintain records that provide a complete audit trail of prescription drugs from purchase to sale or other disposition. Such records known as “pedigree papers” must include a written statement of all previous sales of the drug that is sold in a wholesale market.

SB 2312: 2003 Reform of Florida Drug and Cosmetic Act (the Act)

In 2003 the Legislature revised the Florida Drug and Cosmetic Act to impose more stringent regulation on prescription drug wholesalers.

SB 2312 adopted many of the recommendations of the Seventeenth Statewide Grand Jury report[18] and OPPAGA report[19] on drug diversion. The bill significantly strengthened record keeping requirements for wholesalers and repackagers of prescription drugs. Several of these new “pedigree paper” requirements have a second phase-in period starting July 1, 2006.

The bill created criminal offenses relating to illicit activities involving diversion from wholesale distribution of prescription drugs. Additional prohibitions were created regarding label tampering with the intent to distribute a drug and the distribution of a drug previously dispensed by a Florida-licensed pharmacy. Effective January 1, 2004, the permitting requirements for drug wholesalers were overhauled to require extensive information upon application for a permit, including a criminal history background check, and to require that permits expire annually rather than biennially.

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[16] Drug marketing is also subject to regulation under the Federal Prescription Drug Marketing Act of 1987 which establishes minimum standards for the prescription drug industry that include requirements for an audit trail of sales transactions.

[17] See ss. 499.01 and 499.012, F.S. The permitting requirements for a number of establishments licensed or permitted by the Department of Health to engage in activities regulated under the Florida Drug and Cosmetic Act are the same. Such establishments include: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

[18] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.

[19] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

Track and Trace Technology

According to the U.S. Food and Drug Administration (FDA), it is critical to implement new technologies to better protect the drug supply. In a recent report the FDA concluded, that a combination of rapidly improving track and trace technologies and product authentication technologies could be used to provide a greater level of security for drug products. The FDA has stated that the adoption and wide-spread use of reliable track and trace technology is feasible by 2007.[20]

Track and trace technology refers to many technologies used to track prescription drugs through the supply chain. Two of the most notable technologies are radio-frequency identification (RFID) in combination with an electronic product code (EPC). RFID technology uses a tiny radio frequency chip containing essential data in the form of an electronic product code (EPC).[21] RFID technology is used to tag, identify, and track individual items as they move through the supply chain and into the hands of the buyer or consumer. As the objects move through the supply chain wireless RFID readers can communicate with an RFID tag on the object, collect information about the object (such as a unique number) and match that number in a database to access a complete record about the object. With RFID, product tracking occurs automatically, without the scanning of barcodes.[22] This real-time technology provides speed and accuracy in the supply chain.[23] EPC technology makes it possible to mass serialize all drug products, ensuring each is individually identified and tracked. The FDA continues to play an active role in public and private sector efforts towards developing an "electronic safety net" for our drug supply.[24]

The FDA recognizes that states have implemented and are considering provisions that require a pedigree (in some cases electronic) for drug products. The FDA supports these efforts because they complement federal requirements. Further, the FDA believes that rapid and uniform implementation of a pedigree that starts at the point of manufacture and accompanies the drug product until it is dispensed would be beneficial.[25]

C. SECTION DIRECTORY:

Section 1. – Amends s. 499.006, F.S., to define a prescription drug returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug. Prescription drugs are those regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

Section 2. – Amends s. 499.01, F.S., to require a permit for any person or establishment that intends to operate as a limited prescription drug veterinary wholesaler. The bill provides that the limited drug veterinary wholesaler permit may not be issued to the address of a health care entity or pharmacy licensed under ch. 465, F.S., except as provided in s. 499.01(2)(d), F.S.

Section 3. – Amends s. 499.012, F.S., to establish a limited prescription drug veterinary wholesaler permit. The bill provides several permit requirements and conditions under the permit, including a $20,000 bond or equivalent surety requirement, and provides permissible transactions under the permit.

Section 4. – Amends s. 499.0121, F.S., to provide an alternative to full pedigree paper requirements set to implement July 1, 2006.

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[20] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[21] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[22] Electronic Pedigree for Pharmaceuticals, SupplyScape, 2005.
[23] RFID Technology and EPC in Retail, Symbol, 2004.
[24] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.
[25] Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update, U.S. Food and Drug Administration, May 18, 2005.

Section 5. – Amends s. 499.01221(1)(d) F.S., to delete veterinarians from the group of persons or entities to whom a veterinary legend drug retail establishment may sell veterinary legend drugs. The bill would permit a veterinary legend drug retail establishment to only sell veterinary legend drugs to the public.

Section 6. – Amends s. 499.041, F.S., to require a fee for a limited prescription drug veterinary wholesaler's permit. The bill provides the fee may not be less than $300 or more than $500 annually.

Section 7. – Amends s. 499.065, F.S., to require the Department of Health (DOH) to inspect each limited prescription drug veterinary wholesaler. The bill permits DOH to order the immediate closure of limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health, safety, or welfare.

Section 8. – Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Department of Health Estimates - Limited Prescription Drug Wholesaler Permit

Estimated Revenue	**1st Year**	**2nd Year** (Annualized/Recurr.)
Decrease in permit fee revenue $300 for est. 10 permits	-3,000	-3,000
Total Estimated Revenue	- $3,000	- $3,000

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Alternative to Pedigree Paper Requirements

Proponents of the bill report that implementation of full pedigree paper requirements, without radio frequency identification (RFID), will be a burden to the pharmaceutical industry that will increase the cost of prescription drugs.

Limited Veterinarian Wholesaler Permit

Under the proposed legislation, veterinary wholesalers who wish to offer some legend drugs intended for human use would have the option of obtaining a limited veterinary prescription drug wholesaler permit instead of a prescription drug wholesaler permit. Because the limited veterinary prescription drug wholesaler has fewer requirements than the prescription drug wholesaler permit, some cost savings may be realized. Wholesalers who choose to obtain the newly created permit may pass on their savings to their customers.

D. FISCAL COMMENTS:

Alternative Pedigree Paper Requirements

A fiscal analysis was requested from the Department of Health (DOH), but was not received before this analysis was published. Any information received from DOH will be included in an updated analysis.

Limited Veterinarian Wholesaler Permit

The Department of Health (DOH) estimates that no more that 10 establishments would apply and qualify to become a limited veterinarian wholesaler. As a result, the impact, assuming each is currently permitted as a prescription drug wholesaler or out-of-state prescription drug wholesaler, would be a decrease in revenue of $3,000 annually. According to DOH the $3,000 loss in revenue will have no effect on operations.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Department of Health has the necessary rulemaking authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Pedigree Paper Requirements

Proponents of the bill argue that the phase II pedigree paper requirements set to implement on July 1, 2006 will be burdensome for the industry and may increase the cost of prescription drugs. They also argue that it does not make sense to implement full pedigree paper requirements before the advent of radio frequency identification technology (RFID).

Opponents assert that the phase II regulations will provide added safety to the Florida prescription drug supply. They also argue that requiring pedigree papers for all prescription drug transactions will increase transparency and drive drug diverters out of the market. Opponents feel that full pedigree paper requirements are needed to address the concerns raised in the Seventeenth Statewide Grand Jury report[26] and OPPAGA report on drug diversion.

[26] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES